PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 03511C84	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/IB 03/02946	International filing date *(day/month/year)* 24.07.2003	Priority date *(day/month/year)* 26.07.2002
International Patent Classification (IPC) or both national classification and IPC C08B37/08		
Applicant JASPER LTD LIABILITY CO. et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
10.02.2004	16.09.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Gerber, M Telephone No. +49 89 2399-8528

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IB 03/02946

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-18 as originally filed

Claims, Numbers

1-25 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	7, 8, 10-18, 20
	No:	Claims	1-6, 9, 19, 21-25
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-25
Industrial applicability (IA)	Yes:	Claims	1-20
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1: EP-A-0 555 898 (FIDIA SPA) 18 August 1993

D2: WO 00 01733 A (BELLINI DAVIDE ;FIDIA ADVANCED BIOPOLYMERS SRL (IT); TOPAI ALESSAN) 13 January 2000

1. Novelty

1.1. D1 anticipates the subject-matter of **claims 1-6, 9, 19 and 21-25** (Article 33(2) PCT).

D1 is directed to a medicament comprising a partial or stoichiometrically neutral salt of hylauronic acid with at least one pharmacologically active substance being for instance adenine arabinoside or fluorouracil (see claims 3 and 7). The preparation of the salts is carried out by bringing together solutions or suspensions in water or in organic solvents of the two components or salts thereof (see page 8, lines 5-15, and page 15, lines 21-47).

1.2. The same applies to D2 since this document discloses a salified or simply associated amide derivative of hyaluronic acid with a pharmaceutically active compound derived from purine or pyrimidine (see the passages cited in the international search report and especially page 7, lines 3-6).

2. Inventive step

D1 is considered to represent the most relevant state of the art.

The subject-matter of claim 7 differs from the derivative of hyaluronic acid of D1 in the kind of heterocyclic compound derived from purine and/or pyrimidine chosen to form a salt therewith.

The problem to be solved by the present invention may therefore be regarded as to provide a further derivative of hyaluronic acid with an heterocyclic compound derived from purine and/or pyrimidine.

The list of compounds of claim 7 is believed to provide the same advantages as in D1. Furthermore, the skilled person would regard it as a normal option to include these compounds in the derivative described in document D1 in order to solve the problem posed. In the absence of an effect over the prior art, an inventive step cannot be acknowledged for the subject-matter of **claim 7** (Article 33(3) PCT).

Dependent claims 8 and 10-18, as well as **process claim 20** do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step.

3. Industrial applicability

3.1. The subject-matter of present **claims 1-20** appears to comply with the requirements of industrial applicability as stipulated in Article 33(4) PCT.

3.2. For the assessment of the **present claims 21-25** on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.